DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 8,2015

Vascular Pathways, Inc.
Mr. Scott Pease
Vice President Regulatory Affairs and Quality Assurance
1847 Trade Center Way
Naples, Florida 34109

Re: K142136
Trade/Device Name: AccuCath® Midline Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 20, 2014
Received: November 24, 2014

Dear Mr. Pease:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142136

Device Name

AccuCath® Midline Catheter System

Indications for Use *(Describe)*

The AccuCath® Midline Catheter System is a midline catheter that is inserted into a patient's vascular system for short term use (< 30 days) to sample blood, monitor blood pressure, and administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath® Midline is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 7mL/second.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

AccuCath® Midline Catheter System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Vascular Pathways, Inc.
1847 Trade Center Way
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Cell: 678-689-8010
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Contact Person: Scott Pease, VP of Regulatory Affairs and Quality Assurance
(spease@vascularpathways.com)

Date Prepared: July 31, 2014

Name of Device	AccuCath® Midline Catheter System
Common or Usual Name	Intravascular Catheter
Classification Name	Intravascular Catheter
Product Code / Regulation	FOZ / 21 CFR § 880.5200
Classification	Class 2

Predicate Devices

Bard Access PowerGlide™ Device (K121073)
Vascular Pathways, Inc., AccuCath® BC Intravascular Catheter System (K140504)

Indications for Use

The AccuCath® Midline Catheter System is a midline catheter that is inserted into a patient's vascular system for short term use (< 30 days) to sample blood, monitor blood pressure, and administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath® Midline is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 7mL/second.

Device Description / Technological Characteristics

The AccuCath® Midline Catheter System has a usable length catheter of 3.1 inches in multiple Gauge sizes. The device(s) are single use, sterile intravascular catheters designed to be inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This longer AccuCath® Midline is substantially equivalent functional characteristics and design to the predicates [Bard Access PowerGlide™ Device (K121073) and AccuCath® BC (K140504)]. The AccuCath® Midline catheter hub is identical in design to that of the AccuCath® BC's catheter's hub, including the built-in blood control septum. Additionally, the AccuCath® Midline, like the AccuCath® BC (K140504) predicate, consists of a radiopaque catheter with a blood control valve mechanism that is delivered over a guidewire with atraumatic coiled tip design; a notched needle to enhance flashback visualization, and a body / handle that serves as an integrated safety container to mitigate the risk of sharps injuries. The AccuCath® Midline is identical to the AccuCath BC® in that it features a septum that automatically activates to stop the blood flow in the catheter hub when the needle is removed from the catheter during initial insertion by the clinician. Blood flow from the catheter hub will be restricted immediately after the needle retraction until a secure male luer connection is made. The flow path will remain opened once a secure male luer connection has been made.

Performance Data

Biocompatibility and functional bench testing performed by Vascular Pathways, Inc. demonstrates the AccuCath® Midline Cather is substantial equivalence, in terms of the safety and effectiveness, to the referenced predicate devices. In vitro bench testing included an assessment of all design input requirements and confirmation that the output of the design process met all design input requirements was completed, including those relating to appropriate standards, as follows:

- ASTM D4169-09 – Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F88/F88M-09 – Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929 – Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1980-07 (2011) – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- Guidance Document No. 934 – Medical Devices with sharps injury prevention features (August 9, 2005)

- ISO 594-1:1986 – Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Equipment - Part 1: General Requirements

- ISO 594-2:1998 – Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings

- ISO 7864:1993 – Sterile Hypodermic Needles for Single Use

- ISO 9626:1991 – Stainless Steel Needle Tubing for Manufacture of Medical Devices

- ISO 10555-1:2013 – Sterile, Single Use Intravascular Catheters - Part 1: General Requirements

- ISO 10555-5:2013 – Sterile, Single Use lntravascular Catheters - Part 5: Over-Needle Peripheral Catheters

- ISO 10993-1:2009 – Biological Evaluation of Medical Devices- Part I: Evaluation and Testing

- ISO 11607-1:2009 – Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems, and packaging systems

Summary of Substantial Equivalence

Based upon the device description, technical characteristics and test data provided within this submission, the AccuCath® Midline Catheter System is substantially equivalent to the referenced predicate devices.